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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,451	08/21/2003	Joseph L. Bryant	4115-150 CIP DIV	7909

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
08/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,451	BRYANT ET AL.	
	Examiner	Art Unit	
	MARCIA S. NOBLE	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *12-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/9/2008 has been entered.

Status of Claims

2. Claims 1-21 are pending. Claims 1, 2, 5, and 11 are amended by Applicant's amendment, filed 7/9/2008.

Election/Restrictions

3. Claims 12-21 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/7/2006.

Claims 1-11 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

4. Claims 1-11, as amended and previously presented, stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention,.

Applicant's arguments filed 7/9/2008 have been fully considered but they are not persuasive. Applicant asserts that the amended claims now recite a transgenic rat that expresses at least a portion of a CD4 protein on PBMCs of the rat and that the expressed CD4 is capable of binding gp120. Applicant further asserts that the expression of CD4 on the surface of the PBMCs and the binding of CD4 and gp120 is a predictable phenotype, and therefore the presently claimed transgenic rat has a predictable phenotype. Applicant asserts that the claimed rat may serve as a model for any situation where such binding is present. Applicant also asserts that the working examples teach how to make the double transgenic rats. Therefore, the specification enabled the instantly claimed transgenic rats (p. 7, last par, line 1 to p. 8, par 3, line 3).

Applicant's arguments are not found persuasive for several reasons. First, amended claim 1 is drawn to a transgenic rat that is only required to express a CD4 capable of binding gp120. As applicant asserts, Example 11 provides a means of

making transgenic rat that expresses a CD4 capable of binding gp120 (p. 50, lines 2-24). However, for an invention to be considered enabled by the specification, the specification must provide an enabled means of making an invention and an enabled use for the invention. In the instant case, claim 1 does not have an enabled use. The only intended use disclosed by the specification for the instantly claimed transgenic rat is for use as a model of HIV infection and disease progress (p. 5, lines 14-15). However, the specification teaches CD4 alone is insufficient for HIV infection of rodent cells and that a co-receptor is required (p. 4, lines 7-19). Therefore, because the instantly claimed transgenic rat lacks the co-receptor necessary for HIV infection, the transgenic rat of claim 1 would not be enabled for the intended use as a model for HIV infection and disease progression. Therefore, the specification fails to provide specific guidance to an enabled use for the transgenic rat of claim 1.

Applicant's assertion that "the rat may serve as a model for any situation where CD4 and gp120 binding is present" is not found persuasive because the instant specification does not explicitly or implicitly disclose a model of binding as an intended use for the instantly claimed invention, as previously made of record (see Office Action, mailed 1/9/2008, p. 8, 2nd to last par, line 1 to p. 9, line 3). Therefore, a model of binding of CD4 to gp120 is not an enabled use for the instant invention, because the specification does not contemplate this intended use.

Claims 2-11 are drawn to a transgenic rat comprising two transgenes, CD4 and CCR5 (claims 2-10) or CD4 and CXCR4 (claim 11). As previously made of record, the specification prophetically teaches a transgenic rat with a phenotype of HIV-1 infectivity.

While the methods of making a transgenic rat are established in the art at the time of the invention, the phenotype that will result in such a transgenic rat is unpredictable, as taught by Mullins et al and Houdebine et al (see Office Action, mailed 7/11/2007, p. 7, 1st full par, line 1 to p. 8, line 5). Furthermore, the art teaches of transgenic mouse models expressing CD4 and CXCR4 or CD4 and CCR5 that are not considered predictable models of human HIV-1 as well because addition unknown factors unique to human HIV-1 infection seemed to be involved, as taught by Sawada et al and Browning et al (see Office Action, mailed 7/11/2007, p. 8, 1st full par, line 1 to p. 10, line 2). Therefore, because the phenotype of a transgenic rat with a given phenotype is unpredictable and the art also suggests unknown factors unique to HIV-1infectivity hinder the production of a transgenic animal model for HIV-1 infection, the art teaches that the production of a transgenic rat comprising CD4 and CCR5 transgenes or CD4 and CXCR4 transgene that result in a transgenic rat that can be infected by HIV-1 is unpredictable. Furthermore, because the specification only prophetically teaches the production of a transgenic rat expressing CD4 and CCR5 or CD4 and CXCR4 and the specification fails to provide specific guidance to overcome the unpredictabilities taught in the art, the specification fails to provide specific guidance to enable the production of the claimed double transgenic rat comprising CD4 and CCR5 or CD4 and CXCR4 transgenes with HIV infectivity as intended by the teaching of the specification.

Therefore, because art does not enable a predictable phenotype in a prophetic transgenic rat as claimed and the specification fails to provide specific guidance to make a transgenic rat with a predictable phenotype that can predictably be used for a

intended use disclosed by the specification as a model for HIV infection and disease progress, the instant claims still lack enablement and the rejection of record is maintained.

New Matter

5. The rejection of claims 1-11, rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as set forth in the Office Action, mailed 1/9/2008 (p. 8, par 3, line 1 to p. 9, 2nd to last line), is withdrawn.

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCIA S. NOBLE whose telephone number is (571)272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble

/Peter Paras, Jr./
Supervisory Patent Examiner, Art Unit 1632